

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21:

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 95-R-0002
CUSTOMER NUMBER: 19

FORM APPROVED
OMB NO. 0579-0036

E. LYONS

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

University of Hawaii at Manoa
Office of the Chancellor
Hawaii Hall, 2500 Campus Road
Honolulu, HI 96822

Telephone: (808) 956-6635

INFORMATION

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	1	0	0	1
5. Cats	0	1	0	0	1
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	49	431	11	0	490
8. Rabbits	4	28	0	4	32
9. Non-human Primates	22	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Dolphins	0	5	0	0	5
False Killer Whale	0	1	0	0	1
Monk Seals	0	2	0	0	2

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

DATE SIGNED

10/12/04

Column E Explanation (#1)

1. Registration Number: 95-R-0002 (Customer #19)
2. Number of animals used in the study. 4
3. Species (common name) of animals used in the study: Rabbits
4. Explain the procedures producing pain and/or distress.

COPY FOR
INFORMATION

Four (4) New Zealand White rabbits were used by one University of Hawaii (UH) Principal Investigator (PI) in the continuation of a study entitled "Immune Pathways as Prerequisite for Adjuvants' Efficacies". The overall goal of this study is to assess immunological requirements for adjuvant's efficacies. The PI largely uses mice that are genetically deficient in a number of selected immune mediators and evaluate the immunopotentiating activities of several non-toxic adjuvants in inducing antibody and cell mediated immune responses to a candidate malaria vaccine. The PI extended the evaluation of the efficacies of the adjuvants to rabbits. The PI justifies that a better understanding of the mode of action of adjuvants will allow rational design of the next generation of adjuvants with increased potency and further reduced toxicity

The four rabbits assigned to the E pain and/or distress category were those animals that received Complete Freund's Adjuvant (CFA) which is considered to cause some discomfort at the injection sites. The PI affirms that currently CFA is the only adjuvant they have tested so far in combination with a malaria vaccine that can induce parasite inhibitory antibodies. Since they are comparing the efficacy of different forms of the malaria vaccine in rabbits, they need to use an adjuvant that can reliably induce parasite (malaria) inhibitory antibodies. As such, to compare the efficacy of different vaccines, the PI's research group required the use of CFA.

The rabbits that were treated with CFA **did not** appear to be in any distress during the study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress would interfere with test results. (For Federally mandated testing, see Item 6 below).

If the rabbits that were treated with CFA were observed to exhibit behavior that was associated with pain and/or distress, the animals would have been removed from the study by the PI. **The University attending veterinarian would have then administered pain-relieving drugs and medications.**

The PI explained that adjuvants are once thought of as non-specific potentiators of immune responses. The PI asserts there is mounting evidence that adjuvants can have effects on the quality of immune responses; namely, they can affect the specificity of immune responses. The PI's laboratory found that using CFA together with a malaria vaccine enables animals to develop specific anti-malaria antibodies that kill the malaria parasites. While other non-toxic adjuvants can induce antibodies to the malaria parasites, these antibodies have been do not kill the parasites. CFA is able to induce a special type of antibody that most other adjuvants cannot. One of the research objectives is to replace CFA with other non-toxic adjuvants during immunization with malaria vaccines. Because the PI does not know what kind of antibody will kill the malaria parasites, they need to use CFA as a positive control adjuvant for the malaria vaccines. Therefore, if animals that receive CFA/malaria vaccines do not develop parasite killing antibodies, the PI suspects that the vaccine itself has not been optimized. If other adjuvants in combination with malaria vaccines do not induce parasite killing antibodies, but, the CFA/malaria vaccine does, then the PI can conclude that the non-toxic adjuvants that are being tested are not efficacious. If this is the case, then the research will move on to test other non-toxic adjuvants.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of federal regulations (CFR) title number and the specific section number (e.g., APHIS, CFR 113.102):Not Applicable (N/A)

Agency: (N/A) CFR: (N/A)

OCT 18 2004

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 95-R-0003
CUSTOMER NUMBER: 18

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Queen'S Medical Center
1301 Punchbowl Street
Honolulu, HI 96813

Telephone: (808) -538-9011

COPY

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMN C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0
Unregulated Animals			83		83

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/8/01

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 95-F-0001
CUSTOMER NUMBER: 1205

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Tripler Army Medical Center
Dept. Of Clinical Investigation (Mchk-Ci)
Department Of Clinical Investigation
#1 Jarrett White Road, Bldg 40
Tripler Army Hospital, HI 96859

COPY

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

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4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	0	10	0	10
9. Non-human Primates					
10. Sheep					
11. Pigs	0	0	39	0	39
12. Other Farm Animals					
13. Other Animals					
Ferrets	0	0	14	0	14

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

DATE

7/20/01